PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61F 2/16 — A1

(11) International Publication Number: **WO 96/29956**

(43) International Publication Date: 3 October 1996 (03.10.96)

(21) International Application Number: PCT/US96/04279

(22) International Filing Date: 28 March 1996 (28.03.96)

(30) Priority Data:

08/414,968	31 March 1995 (31.03.95)	US
08/550,223	30 October 1995 (30.10.95)	US

(71)(72) Applicant and Inventor: ANIS, Aziz, Yehia [US/US]; 9540 Firethorn Lane, Lincoln, NE 68520 (US).

(74) Agent: CARNEY, Vincent, L.; P.O. Box 80836, Lincoln, NE 68501-0836 (US).

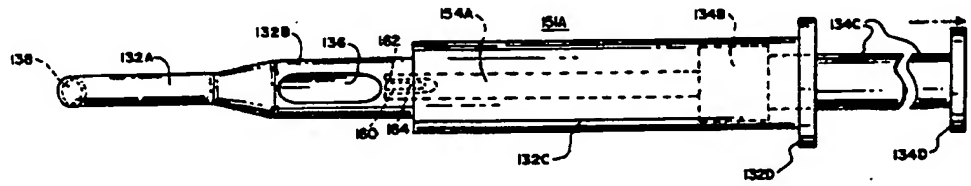
(81) Designated States: CA, JP, European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

Published

With international search report.

Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

(54) Title: INTRAOCULAR LENS IMPLANT AND TOOL FOR IMPLANTING



(57) Abstract

An intraocular lens implant (10) comprising one or more components, each of which has a flexible, substantially ring-shaped position fixation member (20) with a flexible lens body (14) positioned centrally therein. The lens body is connected to the position fixation member by either rim portions or posts (24). To implant the implant, individual components of a coposite lens implant are folded or rolled and inserted through a small incision one-by-one into the capsular sac. Inside the capsular sac, they are opened and positioned together to cooperate in correcting vision. An implantation tool (131A) includes an injection tube (132B) with uniform internal walls corresponding in shape and inside diameter to the external walls of the plunger piston (134A). An entrance opening (136) permits a lens to be depressed into an enlarged portion of the injection tube. It is then pushed forward into the uniform injection tube with a tool (140) before injection into the eye with a plunger.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AM	Armenia	**GB**	United Kingdom	**MW**	Malawi
AT	Austria	**GE**	Georgia	**MX**	Mexico
AU	Australia	**GN**	Guinea	**NE**	Niger
BB	Barbados	**GR**	Greece	**NL**	Netherlands
BE	Belgium	**HU**	Hungary	**NO**	Norway
BF	Burkina Faso	**IE**	Ireland	**NZ**	New Zealand
BG	Bulgaria	**IT**	Italy	**PL**	Poland
BJ	Benin	**JP**	Japan	**PT**	Portugal
BR	Brazil	**KE**	Kenya	**RO**	Romania
BY	Belarus	**KG**	Kyrgystan	**RU**	Russian Federation
CA	Canada	**KP**	Democratic People's Republic of Korea	**SD**	Sudan
CF	Central African Republic			**SE**	Sweden
CG	Congo	**KR**	Republic of Korea	**SG**	Singapore
CH	Switzerland	**KZ**	Kazakhstan	**SI**	Slovenia
CI	Côte d'Ivoire	**LI**	Liechtenstein	**SK**	Slovakia
CM	Cameroon	**LK**	Sri Lanka	**SN**	Senegal
CN	China	**LR**	Liberia	**SZ**	Swaziland
CS	Czechoslovakia	**LT**	Lithuania	**TD**	Chad
CZ	Czech Republic	**LU**	Luxembourg	**TG**	Togo
DE	Germany	**LV**	Latvia	**TJ**	Tajikistan
DK	Denmark	**MC**	Monaco	**TT**	Trinidad and Tobago
EE	Estonia	**MD**	Republic of Moldova	**UA**	Ukraine
ES	Spain	**MG**	Madagascar	**UG**	Uganda
FI	Finland	**ML**	Mali	**US**	United States of America
FR	France	**MN**	Mongolia	**UZ**	Uzbekistan
GA	Gabon	**MR**	Mauritania	**VN**	Viet Nam

INTRAOCULAR LENS IMPLANT AND TOOL FOR IMPLANTING

RELATED APPLICATIONS

This application is a file wrapper continuation-in-part of U.S. patent application 08/414,968, filed March 31, 1995, which is a continuation-in-part of U.S. patent application 08/384,416 filed February 6, 1995, for INTRAOCULAR LENS IMPLANT.

BACKGROUND OF THE INVENTION

This invention relates to artificial intraocular lens implants and tools for injecting them into the posterior capsule of the eye.

In one class of lens implant, an example of which is disclosed in United States Patent 3,866,249, the lens is posteriorly positioned and includes a multiplicity of forwardly projecting prongs. During surgical implantation, the prongs are extended through the iris to anchor the lens in position. While this arrangement maintains positional integrity, it has several distinct disadvantages such as for example: (1) the prongs extending through and over the iris cause irritation: and (2) the fixation points have a tendency to distort the iris by pulling on it in different directions.

Another posterior chamber capsular lens implant is disclosed in United States Patent 4,251,887, issued

February 24, 1981, to Aziz Y. Anis, and in a publication by Aziz Y. Anis entitled "The Anis Posterior Chamber Capsular Lens", Contact and Intraocular Lens Medical Journal, v. 6, n. 3, pp. 286-290, July-September, 1980. This implant has two oppositely directed haptic loops for positioning a lens in the capsular sac. This lens is disclosed as being inserted in the capsular sac using a triangular capsulectomy and sealing the posterior capsule with the two lateral flaps and a small upper flap formed in the triangular capsulectomy. The publication of Anis states that the adhesion of the anterior capsular flaps to the posterior capsule around the optics edge brings the posterior capsule tightly against the posterior rim of the lens edge to prevent cellular migration into and the opacification of the posterior capsule along the optic axis.

This lens and technique has the disadvantage of not being designed to insert the lens implant through an incision smaller than seven millimeters.

One type of tool used when inserting deformable intraocular lens include a guide which receives the deformable lens in a folded shape for insertion into the capsular sac in the posterior chamber. The guide may be inserted into a small opening in the capsular sac and a piston utilized to push the deformed intraocular lens

into the capsular sac for unfolding and permanent implantation.

A prior art type of tool of this class is channel shaped so that the lens may be folded in the channel for injection into the capsular sac. Another prior art tool of this class includes two tubular members. The lens is inserted in a first tubular member and then an outer tubular member is positioned around it. A piston pushes the lens out of the first tube, into the second tube and from the second tube into the capsular sac.

These prior art tools for implantation of intraocular lens have a disadvantage in that the piston tends to grip or catch a portion of the deformable intraocular lens between its surface and the surface of the tube or channel when the lens is being pushed into the capsular sac. This results in a deformation of the intraocular lens in some instances or faulty placement of it in other instances.

Typical prior art tools of this type are disclosed in United States Patent 4,750,498 issued June 14, 1988, to William M. Graham, United States Patent 4,715,373 issued December 29, 1987, to Mazzocco et al., and U.S. Patent 4,634,423 issued January 6, 1987, to Paul F. Bailey, Jr.

SUMMARY OF THE INVENTION

Accordingly, it is an object of this invention to provide a novel lens implant.

It is a further object of the invention to provide a novel technique for implanting lens in the capsular sac.

It is a still further object of the invention to provide a novel lens implant having a central lens body and outer fixation members which can all be folded for insertion through a small opening in the capsular sac.

It is a still further object of the invention to provide a lens implant that may be compressed for insertion through a small incision into the capsular sac without causing localized areas of such high stress in the implant so as to break the implant.

It is a still further object of the invention to provide a composite lens formed of a plurality of individual flexible components, each of which may be separately inserted into the capsular sac.

It is a still further object of the invention to provide a posterior chamber lens that provides substantially complete circular engagement around the capsular sac.

It is a still further object of the invention to provide an implant that spreads tension substantially equally in the wall of the capsular sac.

It is a still further object of the invention to provide a posterior chamber lens which will remain in place even if presssure or force is inadvertently applied to one portion of the lens.

It is a still further object of the invention to provide an improved posterior chamber lens which is designed so that it may be inserted into the eye through a smaller incision than previously possible.

It is a still further object of the invention to provide a novel implant that presses against the capsular wall in a manner that reduces opacification.

It is a still further object of the invention to provide a novel tool for implantation of flexible posterior chamber intraocular lens implants.

It is a still further object of the invention to provide an implanting tool for intraocular lens that is more reliable and less subject to damage of the interocular lens during implantation.

In accordance with the above and further objects of the invention, a flexible lens implant includes a flexible lens body and a flexible holding means such as one or more haptic loops for mounting the flexible lens

implant within the capsular sac. The lens implant is designed to be folded or rolled into a cylinder having a maximum diameter less than five micrometers for insertion through a small opening in the capsular sac and unfolding or unrolling within the capsular sac for positioning.

To aid in inserting the lens into the capsular sac through a small incision, a lens implantation tool includes an ejection opening, a uniform internal diameter tube, a lens entrance opening and a plunger piston. The lens is positioned over the lens entrance and depressed downwardly into the interior of the tube at an enlarged location. It is then pushed into the uniform internal diameter tube.

In one embodiment, the uniform internal diameter tube is then inserted through a small incision into the capsular sac and the plunger piston moved forward to force the lens into the capsular sac. The plunger piston itself has a snug fit with the internal diameter of the uniform internal diameter tube so that there is no space between the outer wall of the piston and the inner wall of the tube sufficient for the lens to be caught between the piston side walls and the internal walls of the uniform internal diameter tube. The piston

end may be curved or flat as long as there is no pinching surface to catch the implant.

In another embodiment, the plunger piston has a compartment at its end with a split bottom and a partialy open top. The compartment is positioned under a portion of the opening in the top of the uniform internal diameter tube so that it lies under approximately half of that opening. The lens is then pushed downwardly so that a portion of it fits in the compartment of the plunger piston and the remainder is within the uniform internal diameter tube. The piston then carries the lens forward. The uniform internal diameter tube is then inserted through a small incision so that it just enters the capsular sac and the plunger piston moves forward to force the lens into the capsular sac within the piston. The piston is rotated so that its slit bottom is upward to protect the top of the capsular sac. The piston is pushed into the capsular sac beyond the uniform internal diameter tube, where its tip expands and the lens unfolds in a predictable and controlled manner.

The flexible lens implant may be shaped as a conventional lens implant, but in the preferred embodiment, it is a flexible composite lens implant that includes a plurality of individual flexible components,

each of which includes a ring-shaped position fixation member or a plurality of fixation members forming a ring and a centrally positioned lens body. The lens body and the fixation member or members may be compressed for insertion through a small incision into the capsular sac without causing localized areas of such high stress in the implant as to break the lens implant.

In these components, the disc-shaped lens body has a front face, a rear face, and an outer peripheral edge. The lens body is thin, flexible and formed as a meniscus lens with one of the front and the rear faces of the lens body being concave and the other convex. The components are designed to be individually folded or rolled for insertion into the capsular sac and unfolded or unrolled in the capsular sac. They are positioned one against the other within the capsular sac and the magnification or correction provided by the composite lens is the result of the curvature of the individual components together, each of which may subtract or add magnefication or other correction to the others.

In the preferred embodiments, a flexible holding means is formed integrally with the lens body and extends therefrom for engagement with substantially the entire capsular equator when the lens is implanted. The flexible holding means may also include any of several

features, such as for example it may: (1) provide fixation of the implant securely without sutures; (2) reduce localized stress on the eye; (3) automatically adjust to changes in eye shape; (4) be compressible to a small size when inserted; (5) be compressible and expandable in a plane passing through the eye when implanted to avoid damage to cells when unfolding; (6) be implantable, without regard to angular orientation about the optic axis; and (7) have reduced breakage because the stress is evenly distributed.

The flexible holding means includes a capsular wall engaging portion and a connecting portion with the capsular wall engaging portion contacting the capsular wall about substantially 360 degrees with a relatively even force to avoid local stresses in the capsular wall while pulling it sufficiently taut to block cellular migration into a location along the optical axis of the eye within the capsular sac. The connecting portion connects the engaging portion of the flexible holding means to the lens body and both the connecting portion and the engaging portion are designed to permit them to be squeezed together in substantially the same plane for insertion through a very small opening without breakage.

The engaging surface may form a completely closed ring about the lens body or may have minor openings

which are compressed relatively closely together in use. The closed ring may be integrally formed as one member or may be formed of crossed loops slightly offset one from the other.

Similarly, the connecting portions may have a number of different shapes generally selected for the purposes of providing: (1) evenly distributed stress in the capsular wall; (2) evenly distributed stress in the engaging and connecting portions when compressed for insertion through a small incision; (3) sufficient strength of the engaging and connecting portions; and (4) ease of intertion into the capsular sac without stressing the zonal connecting tissue.

The connecting portions may extend substantially radially outwardly or be curved or combinations of one or more substantially radial connecting portion and one or more curved portion. The radial connecting portions may either be narrow or relatively wide and the curved portions may be opposed loops or arcs inside the surface engaging member supporting them at different locations. The wall engaging members may either be open at their ends or integrally connected to the lens body at both ends.

The connecting members may position the engaging member to stretch the capsular wall against the convex

posterior surface of the lens body either by: (1) containing an offset that positions the wall engaging portion in a plane parallel to the lens body to maintain a relationship between the posterior surface of the lens body and the holding means that stretches the wall of the capsular sac against the implant to avoid cell migration; or (2) by controlling the size of the engaging portion to provide that stretching.

The flexible holding means accordingly may have any of several shapes such as: (1) a pair of closed kidney-shaped loops extending from opposite sides of the lens body; (2) a radial suppport post extending radially outwardly from the lens body with a pair of open-ended, oppositely-disposed, arcuate fixation elements extending therefrom around substantially the entire peripheral edge of the lens body; (3) a radial support post extending radially outwardly from the lens body with a pair of fixation elements extending around substantially the entire peripheral edge of the lens body and having one end secured to the lens body; (4) a closed ring-shaped fixation element extending from a support post around substantially the entire peripheral edge of the lens body; and (5) a ring-shaped member extending around a centrally positioned lens body with at least one

curved connecting member extending between the lens body and the fixation member.

In any of the embodiments, the flexible posterior chamber lens may be of one-piece construction or may be a composite formed with individual members, each of which member includes its own lens body and fixation member.

From the above description, it can be understood that the intraocular lens implants of this invention have several advantages, such as: (1) each component of a composite lens implant may be compressed to a small size for insertion through a small incision in the capsular wall and expanded for cooperation with each other as a componsit lens implant; (2) a combination of a relatively small number of lens provide a larger number of different corrections because the components of a single composite lens may provide different combinations of additive and subtractive corrections to the composite lens; (3) the implant can adjust to pressures exerted from different angles; (4) they may reside in the capsular sac in a plane substantially perpendicular to the optical axis and with any angular orientation about the optical axis; (5) they provide a uniform force upon the capsular wall to reduce the chances of damaging the capsular wall; (6) some

embodiments reduce opacification by cell migration; and (7) they may be easily inserted without unduly stressing the tissue, such as the ciliary zonule and muscle tissue.

From the above description, it can be understood that the implantation tool of this invention has several advantages, such as: (1) it improves the reliability of the implantation of lens in the posterior capsule; (2) it reduces the incidence of damage to flexible lens when implanted in the eye; and (3) it permits implantation through a very small opening within the capsular sac.

SUMMARY OF THE DRAWINGS

The invention will be better understood from the following detailed description when considered in connection with the following drawings in which:

FIG. 1 is a plan view of one embodiment of the invention;

FIG. 2 is an elevational view of the embodiment of FIG. 1;

FIG. 3 is an exploded perspective view of a composite lens using three component lens of the type shown in FIG. 1;

FIG. 4 is a diagrammatic view showning the method of folding and insertion used in practicing the invention;

FIG. 5 is a fragmentary exploded elevational view of an implant folded for insertion into a capsular sac and a holder for the folded implant;

FIG. 6 is a plan view of one form of the invention with the broken lines indicating various positions of deflection of the position fixation member;

FIG. 7 is a view similar to FIG. 6 except that a further modified form of the invention is illustrated;

FIG. 8 is a plan view of a modified form of the embodiment of FIG. 1;

FIG. 9 is a plan view of another embodiment of the invention;

FIGS. 10, 11 and 12 are side views representative of forms that may be taken for the other embodiments and illustrating a meniscus type lens;

FIG. 13 is a plan view of still another embodiment of the invention;

FIG. 14 is a side view of the embodiment of FIG. 13;

FIG. 15 is a side view of another embodiment of the invention with broken lines indicating different positions of deflection;

FIG. 16 is a plan view of one form of the invention;

FIG. 17 is a side view of the lens of FIG. 16;

FIG. 18 is a plan view of still another embodiment of the invention;

FIG. 19 is a plan view of still another modified form of the invention;

FIG. 20 is a side view of the lens of FIG. 19;

FIG. 21 is a plan view of a modified form of the invention;

FIG. 22 is a plan view of still another modified form of the invention;

FIG. 23 ia a plan view of still another modified form of the invention;

FIG. 24 is a plan view illustrating an incision being created during the implantation process;

FIG. 25 is a view similar to FIG. 23 but which illustrates an implant or component of an implant being implanted;

FIG. 26 is a view illustrating the lens implant after it has been implanted;

FIG. 27 is a sectional view illustrating the lens of this invention implanted in the posterior chamber;

FIG. 28 is an elevational side view of an implantation tool containing a flexible intraocular lens in accordance with an embodiment of the invention;

FIG. 29 is a plan view of the implantation tool of FIG. 28;

FIG. 30 is a front elevational view of a positioning tool useful in connection with the implantation tool of FIGS. 28 and 29;

FIG. 31 is a side elevational view of the positioning tool of FIG. 30;

FIG. 32 is a fragmentary elevational view of the implanting tool showing a stage in the loading of the implantation tool with an intraocular lens;

FIG. 33 is a fragmentary elevational view of the implanting tool showing another stage in the loading of the implantation tool of FIGS. 28 and 29;

FIG. 34 is a fragmentary elevational view of the implanting tool showing still another stage of the loading of the implantation tool with a lens;

FIG. 35 is a fragmentary elevational view of the implanting tool showing still another stage of the loading of an intraocular lens into the implantation tool of FIGS. 28 and 29;

FIG. 36 is a plan view of another embodiment of implantation tool similar to the embodiment of FIG. 29;

FIG. 37 is a fragmentary elevational view of the implanting tool of FIG. 36 showing still another stage of the loading of the implantation tool with a lens; and

FIG. 38 is a fragmentary elevational view of the implanting tool of FIG. 36 showing still another stage of the loading of the intraocular lens into the implantation tool.

DETAILED DESCRIPTION

In FIG. 1, there is shown an embodiment of lens 10B, which may be a component for a composite lens implant 11B (FIG. 3) at a first thickness or an integral lens implant having a second larger thickness, at least twice the thickness of the first thickness. It has a pair of opposing connectors 22B and 24B extending from the lens body 12 to the position fixation member. The position fixation member is a closed circle and may be in a single plane or angled upwardly but should be sufficient distance from the apex of the lens body 12 to cause it to press against the capsular wall.

The construction of the lens implant 10B is such that the fixation member 20B and lens body are made of a flexible material such as silicon and may be compressed or rolled into a small cylinder for insertion into the capsular sac through a small incision. At least

portions of each of the lens body and of the position fixation member are sufficiently flexible to be folded to form an arc of at least thirty degrees and the combination of fixation member and lens body must be sufficiently flexible to form an arc of at least 360 degrees.

In FIG. 2, there is shown an elevational view of the embodiment of FIG. 1, designed for use as a component of a multiple component implant having parts labeled with identical reference numerals as those in FIG. 1. In this embodiment, the lens 10B includes a fixation member 20B and a disc-shaped lens body 12 having a front face, a rear face, and an outer peripheral edge. The lens body is thin, flexible and formed as a meniscus lens with each of the front and the rear faces of the lens body being concave or to form the meniscus lens. The fixation member 20 is ring shaped and is held to the lens body 12 by radial connecting means 22B and 24B.

The lens component 10B is designed to be individually folded or rolled for insertion into the capsular sac and unfolded or unrolled in the capsular sac. Within the capsular sac, it is unfolded or unrolled and positioned against other components to contribute to the magnification or correction within the

capsular sac. The positioning member 20B is formed integrally with the lens body and extends therefrom for engagement with substantially the entire capsular equator when the lens is implanted.

In FIG. 3, there is shown an exploded perspective view of a multiple-component lens implant 11B including three identical components 13A, 13B and 13C, arranged to overlie each other within the capsular sac. The three components 13A, 13B and 13C include corresponding ones of the lens bodies 15A, 15B and 15C, positioning rings 21A, 21B and 21C and connecting members 17A, 19A, 17B, 19B and 17C, 19C mounted together as described in connection with FIG. 2. The lens bodies 15A, 15B and 15C cooperate to add correction for farsightedness, nearsightedness, and/or astigmitism and may provide different corrections at the top and the bottom to simulate bifocals. To permit easy folding into small rolls for insertion into the capsular sac, the fixation members and lens body and connecting members are all thin, being less than 0.01 mm (millimeter) in thickness in the preferred embodiment.

In FIG. 4, there is shown anothor embodiment of multiple component implant 11C having two components 13D and 13E, designed to cooperate by overlying each other. However, in the embodiment of FIG 4, one of the

components 13D, provides positive correction and the other component, 13E, provides negative correction. Thus, the components cooperate in a subtractive sense. Similarly, the components may both provide negative correction or any other combination of corrections and may include any number of components to a single implant.

As in the embodiment of FIG. 3, the components 13D and 13E include corresponding lens bodies 23A and 23B (the lens body 23A providing positive correction and the lens body 23B providing negative correction).

In FIG. 5, there is shown a fragmentary simplified elevational view of a holder 131 and rolled lens component 13A. The component 13A may be rolled, inserted in the holder 131 and inserted through an opening in the capsular sac for removal in a manner known in the art. Because the lens body is flexible, and in some embodiments formed of separately insertable components, a small opening can accommodate a relatively thick lens.

In FIG. 6 there is shown another embodiment of posterior chamber lens implant or component of a lens implant 10 having a ring-shaped position fixation member 20 positioned outwardly of the flexible lens body 12 and connected thereto by a pair of elongated curved

connecting members 22 and 24 which extend oppositely from the lens body 12. The connecting members 22 and 24 aid in centrally positioning the lens body 12 with respect to the fixation member 20.

In the preferred embodiment, each of the members 22 and 24 has a portion thereof which is generally concentrically positioned with respect to the fixation member 20 and which is referred to generally by the reference numerals 26 and 28 respectively. However, other angles may be used in line with the purpose of permitting the fixation member 20 to be compressed towards the lens body 12, as illustrated by the broken lines and thus enable the implant 10 to be inserted into the capsular sac through a small aperture.

Because the angles are of a relatively small size and are substantially within the plane of the lens, they provide reduced areas of excessive stress and strain on the attachment members that connect the fixation member to the lens. Because the fixation members make appropriate angles with both the lens body and the fixation member, when they are compressed, there is no portion of them which is compressed to such a greater degree than other portions as to be subject to early failure.

In the embodiment 16A shown in FIG. 7, the fixation member 22A extends completely around the lens body 12 and is connected thereto by a pair of elongated curved connecting members 22A and 24A which extend oppositely from lens body 12. Essentially, connecting member 24A extends from the three o'clock position to the nine o'clock position while connecting member 22A extends from approximately the nine o'clock position to the three o'clock position.

The embodiment 10A of implant shown in FIG. 7 is substantially the same as that shown in FIG. 6 except that the connecting members are slightly longer and have a longer portion of their length concentric to the periphery of the lens body. In all of the embodiments, the fixation members may dwell in the same plane as the lens body as illustrated in the drawings or they may be offset therefrom. The increased length of the connecting members reduces the stress and strain when they are compressed together inwardly toward the lens body for insertion into the capsular sac through a small incision by reducing the angle at start of the connecting member with the fixation member and with the lens body.

In FIG. 8, there is shown an embodiment 10C of lens implant or lens implant component identical to lens

implant 10C except that the posts 22C and 24C have a greater width than the posts 22B and 24B (FIG. 1). By increasing the width of the posts 22C and 24C, greater stability of the lens implant is achieved. During implantation, the fixation member 20C is compressed towards the lens body 12 and the posts 22C and 24C prevent the fixation member 20C from "bulging out" in the vicinity of the posts.

In FIG. 9, there is shown still another embodiment of implant, 10D, illustrating connectors 22D and 24D in a limiting condition between the radially extending connecting members 22B and 24B of FIG. 1 and the curved connecting members 22A, 24A and 22 and 24 of the embodiments of FIGS. 7 and 6, respectively. In the embodiment of FIG. 9, the fixation member 20D is a full circle but it is connected by straight connectors tangential to the lens body to provide equal angles between the fixation member and the lens body to minimize stresses of compression and a short connecting member because it is not curved which still permits easy compression in a plane rather than applying buckling forces.

In FIGS. 10, 11 and 12, there are shown in elevational views three structures for any of the embodiments 1-9, 13-23 or 26-29 permitting the apex of a

lens body 12 to contact the bottom of the capsular wall, which structures are respectively: (1) a structure in which the posterior located apex 23 is posterior to the fixation member and the fixation member is anteriorly to its outer perifery 21 a sufficient distance to permit the apex 23 to contact the end of the capsular wall; (2) the posteriorly located apex 23 is part of a lens body which is below the fixation member and the fixation member is curved to permit the apex to contact the capsular wall; and (3) the apex 23 is part of a convexoconvex lens body 12 with the fixation member being in a center plane but sufficiently far in the anterior direction from the apex 23 to permit the apex 23 to contact the wall of the capsular sac. Of course, other configurations may be derived using the above examples to arrive at the appropriate tension of the capsular wall against the lens implant that prevents cellular migration to the optical axis. Each of these lens is a meniscus type lens with the inner surface shown at 13 so as to provide a selected power.

In FIGS. 13 and 14, a lens implant 10E is shown having a centrally positioned lens body 12 with a pair of opposing loop members secured thereto and extending therearound. One of the loop members extends substantially tangentially from the lens body at

approximately three o'clock and continues around the lens body in a spaced-apart relationship with respect thereto. The other end of the loop member is connected to the lens body at approximately three o'clock. The other loop member extends substantially tangentially from the lens body at approximately nine o'clock and continues around the lens body in a clockwise direction in a spaced-apart relationship thereto with the other end of the other loop member being connected to the lens body at approximately nine o'clock. The means for connecting the loop members to the lens body permits the loop members to be compressed relative to the lens body to facilitate insertion of the implant into the eye.

Preferably, loop members 20E and 22E dwell in slightly different planes so that they may intersect without substantial contact at 24E and 26E although the loop members 20E and 22E may be positioned in the same plane if desired which will require that the loop members "cross-over" at 24E and 26E. Further, the loop members 20E and 22E may be offset with respect to the lens body. Generally the offset from the lens body, closeness to the same plane of the loops, and the number of degrees around the periphery of the lens body through which they extend are selected to permit substantially 360 degree contact with the capsular wall and tension of

the capsular wall in accordance with the principles of the above embodiment.

In the embodiments of FIGS. 1-4 and 6-14, the fixation member is shaped as a complete ring to provide 360 degree contact of the fixation member with the capsular wall. The fixation ring and the lens body are constructed and positioned to provide equal tension along the capsular wall while pulling it against the lens to prevent cellular migration in the capsular sac to reduce light passage along the optical axis of the eye. While the function of the fixation members are the same in each embodiment, the specific designs of the fixation member in the different embodiments differ one from the other to provide special characteristics for each.

In FIGS. 15-25, there are shown a number of embodiments of the invention in which the fixation members do not extend completely around the lens body but nonetheless contact the capsular wall through a sufficient number of degrees and have a wall engagement portion in a plane sufficiently offset from the parallel plane of the apex of the convex portion of the lens body to permit the capsular wall between the apex and the wall engaging portion to be in tension.

In the embodiment 10H shown in FIG. 15, the fixation member 20H does not extend completely around the lens body 12 but is provided with a slight gap referred to generally by the reference numeral 30. As shown in FIG. 14, a pair of parallel posts 32 and 34 extend generally radially outwardly from lens body 12 and are connected to the substantially ring-shaped fixation member 20H. A single curved connecting member 25H connects lens body 12 with the member 20H substantially opposite the posts 32 and 34.

In the embodiment of FIG. 15, the fixation member 20H engages the wall of the capsular sac for almost 360 degrees. The posts 32 and 34 and the connecting member 25H aid in centrally positioning the lens body 12 with respect to the fixation member 20H. This construction of the lens implant permits the fixation member 20H to be compressed relative to the lens body 12 for insertion into the capsular sac as illustrated by broken lines in FIG. 15. The 360 degree engagement of the fixation member 20H with the eye positively ensures that the lens implant remains in position and does not become inadvertently dislodged. The lens implant of FIG. 15 functions similarly to that of the embodiments previously described.

FIGS. 16 and 17 illustrate one form of the lens structure 10I having a disc-shaped lens body 12 and fixation elements 20I and 21I integrally formed with lens body 12 and extending from the periphery thereof. As shown in FIG. 17, the outer end portions of fixation elements 20I and 21I dwell in a plane forwardly of the convex face 14. Although the design of the fixation element or elements varies from embodiment to embodiment, all of the fixation elements are disposed so that the outer ends thereof engage a substantial portion of the capsular equator when the lens is implanted.

FIG. 18 illustrates a lens implant 10J having fixation element 24J with portions 20J and 21J joined or secured to the lens body 12 by curved connectors 22J and 23J at approximately twelve o'clock and connected by radial post 25J at the other end. FIGS. 19 and 20 illustrate yet another lens implant 10K comprising a disc-shaped lens body 12 having convex rear or posterior face 14 and front or anterior face 16. Fixation elements 20K and 21K are integrally formed with lens body 12 and are substantially semi-circular shaped in plan view so that the fixation elements extend around the entire peripheral edge.

Fixation element 20K includes support posts 22K and 24K extending from the lens body 12 and fixation element

21K includes support posts 23K and 25K extending from the lens body. The support posts 22K, 24K and 23K, 25K extend anteriorly or forwardly from the lens body as illustrated in FIG. 19 so that the outer end portions of the fixation elements dwell in a plane forwardly of the face 14 as in the other embodiments. If desired, the support posts could extend forwardly at right angles to the face 14 and thence outwardly to enable the outer end portions of the fixation elements to dwell in a plane forwardly of the face 14.

In FIG. 21 there is shown another embodiment of lens implant 10L having a support post 22L that extends radially outwardly from lens body 12 and has a pair of fixation elements 20L and 21L extending therefrom around substantially the entire peripheral edge of the lens body in a spaced-apart relationship. This embodiment permits the insertion of the implant 10L with the post 22L being inserted through the incision first. Moreover, when the structure of FIG. 21 is a component of a composite implant, it may be folded or rolled over a central exis along post 22L for a smaller roll. The post 22L provides sufficient stiffness to move the implant 10L against the capsular wall without excessive bending from the horinzontal of the implant. The open ends 41L and 43L may be moved inward and over each other

to insert them through the incision and allow them to spring back against the capsular wall so that excessive pressure is not needed to complete the implant, thus avoiding damage to the tissue.

In FIG. 22 there is shown another embodiment 10M of the lens implant wherein a single fixation element 20M extends from the lens body so that the end 41M of the fixation element 20M terminates closely adjacent the support post 22M. In FIG. 23, there is shown an embodiment of lens implant 10N having fixation elements 20N and 21N extending from opposite points on the lens body 12 and being so that they extend substantially around the entire peripheral edge of the lens when compressed.

The lens implant of this invention is inserted or implanted as follows. As shown in FIG. 24, an incision is created with the incision being shorter than would normally be required. As shown in FIG. 25, a holder or implantation tool 131 is inserted through the opening an a component of a lens implant such as 13A or any other completely flexible implant or component of lens implant is inserted with the holder as shown in FIG. 25. After the implant component 13A is deposited within the capsular sac from the holder 131 it is unfolded and positioned as shown in FIG. 26.

In FIG. 27, the numeral 11 refers to an eye, after cataract removal by surgical procedure. Eye 11 includes a cornea 13 which merges into an opaque protective covering 15 called sclera. Behind the cornea 13 is the iris 17 which defines a central opening 19 known as the pupil. The iris 17 comprises a muscular diaphragm-like element capable of expansion and contraction to control the amount of light passed therethrough. The iris divides the internal chamber of the eye into two chambers, the anterior chamber 31 and the posterior chamber 33.

The natural crystalline lens of the eye is located in the posterior chamber 33 adjacent the pupil 19. After the natural lens has been surgically removed, a relatively flattened posterior capsule or membrane 35 remains. Normally, a small part of the anterior capsule also remains and is referred to generally by the reference numeral 37 in FIG. 27.

In the prior art implants, the posterior capsule 35 is not in close engagement with the lens implant and cells tend to migrate onto the posterior capsule which causes the opacification of the posterior capsule. However, the implants of this invention are held in position with the fixation members against the capsular

wall and the lens face pressing against the bottom along the optical axis.

The embodiments of FIGS. 6, 7 and 15 have several advantages, such as: (1) because the angles the connecting members make with the fixation member and with the lens body are acute, these embodiments permit flexibility without excess strain; (2) they provide ease of insertion through the incision; and (3) they permits flexibility because the open ends fold over each other for insertion.

In all of the lens embodiments described hereinabove, the lens body and the fixation element or elements of each component of a composite lens are preferably of unitary one-piece construction. Preferably, the lens material and the fixation elements are comprised of flexible silicon material, but in some embodiments, the fixation members may be comprised of polypropylene or other flexible material.

Further, all of the fixation elements are designed so that the fixation element or elements engage substantially the entire capsular equator when the lens is implanted to aid in properly positioning the lens and to aid in maintaining the lens in position after implantation. Preferably each component of a composite lens has a fixation element that engages substantially

the entire capsular equator but at least the combination of components engages the capsular equator. In each of the lens embodiments, the convex rear face thereof engages the posterior capsule to stretch the same rearwardly so that close engagement is achieved therebetween to prevent cellular migration onto the posterior capsule thereby preventing opacification of the posterior capsule.

In a preferred embodiment: (1) the lens body has a diameter of 6 millimeters but it can be between 4.0 and 8.0 millimeters; (2) the diameter of fixation member is 10.5 millimeters but it can vary between 8.0 millimeters and 13.0 millimeters; the diameter of the fixation member and posts of each component lens are sufficiently small to be flexible enough such that, considering the small size and flexibility of the lens body, the implant or component lens of a composite lens can be inserted into the capsular sac through an incision shorter than 7 millimeters.

There are several structural features in each of the above-described embodiments that affect certain desirable characteristics. The desirable characteristics include: (1) more flexibility; (2) little or no bulging during implantation; (3) more structural strength and resistance to breakage after

implantation; (4) perfect centration and stability; and (5) better prevention of opacification by cell migration after implantation. The structural features are: (1) curved connection members; (2) elongated connection members; (3) elongated fixation members; (4) wider or narrower connection members; (5) wider or narrower fixation members; (6) singular or multiple fixation members; (7) singular or multiple connection members; (8) open or close-ended fixation members; (9) number of degrees covered by the fixation member or members to create a circle; and (10) the number of components of a composite lens.

Flexibility can be affected by one or more of several factors: (1) straight or curved connection members; (2) angles between the connection member and the fixation member; (3) angles between the connection member and the lens body; (4) length and width of the connection member; (5) length and width of the fixation member; (6) number of supports or connection members for the fixation member; (7) the flexibility of the lens body; (8) the number of components that make up a composite lens; and (9) whether the fixation member has an open or closed end.

The length of the radius of curvature affects the flexibility of the connection member because a

connection member with a short radius of curvature is more flexible than a connection member with a long radius of curvature. Therefore, a lens implant with curved connection members is more flexible than a lens implant with connection members that are straight posts. If the length of the curve of the connection member is longer, which would make the degrees of the angles between the connection member and the fixation member and/or the degrees of the angles between the connection member and the lens body higher, more flexibility is added to the connection member.

The length of the curve, the angle with which the connection member meets the lens body, and the angle with which the connection member meets the fixation member are dependant on the radius of curvature. A connection member with a radius of curvature that is too short connects the fixation member or the lens body at an angle that is too acute and less flexible, and never connects the flexible member to the lens body. Moreover, the connection member forms either a complete circle or attaches back to the member with which it is already connected. However, if the radius of curvature of the connection member is made longer, the length of the curve is made longer and if the radius of curvature is long enough, it provides a connection between the

lens body and the fixation member. The lens implant is therefore more flexible if the connection members have a shorter radius of curvature yet long enough to have a longer length of curve in inches or in degrees before connecting the lens body to the fixation member.

The center of the radius of curvature of opposing connection means also affects the flexibility of the connection means because if the centers of the radius of curvatures of opposing connection means are closer to or in the lens body, more flexibility is obtained.

Another factor which affects flexibility is the width of the connection members because a wide connection member, when compressed for implantation, is stiffer than a thinner connection member because there is more structure that has to bend. The fixation members are all curved to enable the lens implant to substantially engage the entire capsular equator of the capsular sac. The length and width of the fixation member can increase the flexibility of the lens implant. A long fixation member has more flexibility than a short fixation member and a thinner fixation member is more flexible than a wider fixation member. The combination of a long, thin fixation member increases its flexibility.

The number of connection members affects the flexibility of the lens implant because the connection members tend to restrict flexibility at the positions they are connected to the fixation member. Multiple fixation members in a lens implant are usually shorter fixation members and are less flexible than the implants with fewer and longer fixation members. Further flexibility can be added to a lens implant with multiple fixation members by increasing their lengths. However, when there are two or more flexible members and they are not connected to each other at the connection members, more flexibility is achieved. If a fixation member has an open end, its flexibility is also increased because the open end is free to move in the direction of compression.

Strength and resistance to breaking of the lens implant after insertion into the capsular sac is also important. A lens implant with a wider fixation member or connection member is less likely to break after insertion into the capsular sac and shorter fixation members and connection members are more resistant to breaking. Moreover, reducing the strain during flexing reduces breakage. This can be done with curved connection members.

After the lens implant is implanted, a concern is the extent of cellular migration to the optical axis of the capsular sac. If the fixation member of the lens implant presses against the walls of the capsular sac at a 360 degree circumference, cellular migration is less likely to occur. However, even though some of the fixation members do not complete a 360 degree outer perimeter, the lens implant, after implantation may still be compressed enough to close the gap between multiple fixation members or fixation members with an opening, thereby engaging substantially the entire capsular equator of the capsular sac.

To obtain the optimum result, the above-described features should be considered and weighed before deciding which implant should be used. A lens implant with open-ended fixation members is more flexible but cellular migration has a greater chance of occuring after implantation. However, cellular migration can be decreased without reducing the flexibility of components of a composite lens by using overlapping components that combine inside the capsular sac to block migration by forming a complete circle but are individually open ended to be more easily rolled for insertion. A lens implant with two fixation members and four connection members is somewhat flexible, may have some bulging

during implantation, but because there is very little space between each pair of posts, it has less of a chance of cellular migration after implantation.

Lens implants with thicker connection members attached to the fixation member add more strength to the lens implant after insertion but are not as flexible as other lens implants and therefore requires a longer incision in the capsular sac. However, using multiple components permits the use of a composite with the additive strength of several connection means in layers but with each individual component being flexible for insertion and individual flexing in the capsular sac. An opening can be made in the fixation member which allows the implant to be inserted into a smaller incision but may allow cellular migration through a furrow which may be created by the lack of structure at the opening.

Each of implants has a corresponding one of a plurality of flexible, substantially ring-shaped position fixation members extending around a corresponding one of a plurality of disc-shaped lens bodies. Each of the lens bodies may have the same structure and are referred to by the same reference number 12 hereinafter. Each of them: (1) has a diameter less than the position fixation element; (2) may be of

the planoconvex or convexoconvex or concavoconvex configuration; and (3) has a front or anterior face, back or posterior face and a peripheral edge. The means for connecting the lens body to the fixation member also permits the fixation member and lens body to be compressed to facilitate insertion of the implant into the eye through a small incision.

In this description, the fixation member or element is part of a lens holding means, which includes the fixation member or element and the connecting member or element that connects the fixation member to the lens. The fixation or position fixing member is also referred to as a wall engaging portion of the holding means because it contacts the inner wall of the capsular sac.

While the fixation members and flexible connection means in each of the embodiments of the invention generally have the same function, they differ in construction and to some extent other features from embodiment to embodiment. In all cases they are intended to be sufficiently flexible to permit compression in the plane of the lens or rolling for ready insertion and to be sufficiently close to being circular in nature and of a sufficient number of degrees of arc to substantially contact an entire circle of the inner capsular wall and to be sufficiently symmetrical

to provide some self-adjusting and centering of the lens body.

The substantially complete circle of contact with the inner capsular wall spreads stresses along the wall so that there are no points of stress that are substantially greater than other points along the contacting surfaces. Moreover, they evenly stretch the capsular wall to hold enough of the capsular wall around the optic axis against the surface of the lens to prevent cellular migration and opacification of the capsular wall in line with the optic axis. As can be understood, the many features of the lens implants which can be selected can be combined in different ways to obtain different optimums.

In FIG. 28 there is shown an elevational view of an implantation tool 131A containing within it a lens 10I positioned to be implanted in the capsular sac of a patient. The implanting tool 131A includes an injector tube and a plunger. The injector tube has a uniform internal diameter injector section 132A, an enlarged lens entrance section 132B a handle section 132C and a closing end member 132D. The plunger includes a piston 134A, a plunger stabilizing portion 134B, a plunger base portion 134C and an end member 134D.

In the preferred embodiment, the uniform internal diameter section 132, the enlarged lens entrance section 132B and the handle section 132C are integrally formed and have an aligned central axis through a continuous opening. The end member 132D includes a central opening adapted to permit sliding of the plunger base 134C through it but smaller than the diameter of the plunger end piece 134D to limit movement of the plunger from passing into the handle portion 132C. The piston portion 134A has an external diameter conforming substantially to the internal diameter of the injector tube 132A so as to have a snug fit and avoid any opportunity for a lens such as the lens 10I to get caught between the external walls of the piston portion 134A and the internal walls of the diameter tube 132A.

The face of the piston portion 134A that contacts the lens 10A may be flat, convex or concave but if it is convex it should not form a bite around its external periphery with the internal walls of the uniform tube 132A that could catch the thin membrane forming a portion of the lens 10A. An ejection opening 138 is at the distal end of the uniform tube portion 132A and is at an angle to eject the lens 10I angularly into the capsular sac, where it may unfold. The lens such as the lens 10I is formed of a material having a memory so as

to unfold after it is compressed within the implanting tool 131A.

The opening 136 is elliptical and sized so that the lens may be moved into it easily while the lens is automatically folded by being depressed into the slot. The stabilizing section 134B forms a tight fit with the enlarged inner diameter of the handle portion 132C of the injection tube and is mounted movably so as to provide a point of stability to the piston 134A in cooperation with the close fit between the central opening in the end piece 132D of the injection tube and the plunger base 134C which is substantially uniform. This provides stability to the tube to permit better alignment. The enlarged section 132B for the opening slants downwardly to the uniform tube portion 132A and its internal diameter so as to provide a still smoother transition for both the lens 10I and the plunger 134A. In the preferred embodiment, the uniform internal diameter section 132A of the injection tube and outer diameter of the plunger piston 134A are each two millimeters and the outer diameter of the uniform internal diameter section is 3.2 millimeters. The major diameter of the lens entrance opening 136 and the length of the positioner are each 10.5 millimeters.

In FIG. 29, there is shown a plan view of the implantation tool 131A showing the generally circular lens ejection opening 138 and the external wall of the uniform tubular portion 132A. In this view, the generally elliptical entrance opening 136 and the enlarged lens entrance section 132B is shown having a major axis slightly longer than the diameter of an intraocular lens and its binar axis considerably shorter to force folding of haptics when the lens is depressed through the entrance 136 into the enlarged entrance tube 132B. As shown in this view, the piston portion 134A of the plunger is pulled backwardly out of the way of the lens-entrance opening 136 so as to not impede insertion of a lens. It is pulled back by the handle 134C.

In FIG. 30 there is shown a front elevational view of a positioning tool 140 having a depressing section 142, a pusher portion 144 and a rounded tip 146. The depressor is relatively wide and has a width in one dimension slightly shorter than the major axis of the opening 136 (FIGS. 1 and 2). The pusher portion 144 is very narrow and thin and ends in the rounded portion 146 shaped so as to not pierce a thin flexible lens membrane.

In FIG. 31, there is shown a side elevational view of the positioning tool 140 showing that the depressor

portion or section 142 is relatively thin so as to be able to push a lens through the opening 136 (FIGS. 1 and 2) and the pusher portion 144 is rounded.

In FIG. 32, there is shown in a fragmentary view a first position for inserting a lens 10I through the entrance 136. As shown in this view the plunger 134A is withdrawn to clear the opening 136 and the lens may be laid over the opening so that the opening along its major axis extends beyond the lens but the lens overlies the enlarged entrance portion 132B of the injector tube along a direction parallel to the minor axis of the opening 136.

As shown in FIG. 33, which is an elevational view, the depressor portion 142 of the positioning tool 140 is inserted aligned with the major axis of the opening 136 over the lens 10I for pushing it downwardly as shown in FIG. 34 into the enlarged entrance section 132B of the injector tube. As it does this, the lens fold over so that the haptics which are laid in a direction overlying the tube with the axis through the two haptics being transverse to the longitudinal axis of the injector tube.

With this arrangement, the lens is folded over and the haptics and lens form a cup shaped configuration within the enlarged section. The positioning tool 140

is then reversed so that the depressor portion 142 is slanted upwardly and the pusher portion 144 extends downwardly with the rounded end 146 within the lens 10I. In this position the relatively large flat portion 142 may be grasped by the surgeon and the lens pushed into the uniform tubular portion 132A of the injector tube. The plunger 132 may now be moved forwardly and, since the outer diameter matches the inner diameter of the uniform portion 132A, the lens is not caught in any slanted portion but instead is moved smoothly forward for injection into the eye with high reliability.

In FIG. 36, there is shown a plan view of another embodiment of implantation tool 151A similar in all respects to the embodiment of FIGS. 28-35 except for the distal end of the piston 154A which differs from the end portion of the piston 134A described in connection with FIGS. 28-35. In the embodiment of FIG. 36, the end portion of the piston 154A extends inwardly for a length of approximately half the length of the major axis of the elliptical opening 136. Thus, the length of the compartment is 5.25 millimeters.

This distal end of the piston 154A is recessed to form a compartment or chamber 160 having thin walls 162 and an opening at the top larger than the width of the depressing section 142 (FIGS. 37 and 38) of the

positioning tool 140 (FIGS. 37 and 38) and of the diameter of the rounded tip 146 (FIGS. 30 and 31) of the positioning tool 140, whichever is greater. It has a width large enough to accommodate the two end portions of the positioning tool 140 but sufficiently short to form lips on the edges of the walls 162 tending to partially close the chamber 160. Along the center of its bottom wall is an elongated slit 164 extending along substantially its entire length.

As best shown in FIGS. 37 and 38, the lens 10I may be inserted in a similar manner to that of the embodiments of FIGS. 28-35 using the implantation tool 151A as with the embodiment of FIGS. 28-35. However, with the embodiment 151A, the piston 154 is pushed so that the chamber 160 is underneath the opening 136 and its distal end is at the midpoint of the opening 136 so that it faces upwardly across half of the opening 136. The opening at the top of the chamber 160 conforms to the minor axis of the opening 136.

With the piston 154A positioned properly, the implant 10A is positioned as shown in FIG. 2 and the positioning tool 140 is pressed downwardly as shown in FIG. 37 to fold the implant 10A with half of it being within the chamber 160. Then with the aid of the opposite side of the positioning tool as shown in FIG.

38, using the ball 146 (FIGS. 30 and 31) at its end and moving the piston 154A forwardly into the section 144, the piston 154A is moved so that the implant is located as shown in FIG. 38, half within the compartment 160 and half within the tubular portion 132A. The plunger is then rotated through 180 degrees so that the opening of the compartment 160 faces against the wall of the tubular portion 132A and the slit 164 faces in the same direction as the opening 136.

The lens implant is inserted as shown in FIGS. 24-27 by making an incision, inserting the implantation tool 151A close to the incision in the capsular sac so that it is at its entrance, depressing the plunger so that the chamber 160 moves into the capsular sac with its upper wall protecting the upper wall of the capsular sac and the slit 164 opens to release the lens. In this manner, the lens unfolds as it obtains room within the chamber and is properly positioned without unfolding toward the upper wall of the capsular sac.

From the above description, it can be understood that the intraocular lens implants of this invention have several advantages, such as: (1) they may be compressed to a small size for insertion through a small incision in the capsular wall; (2) they can adjust to pressures exerted from different angles; (3) they may

reside in the capsular sac with any orientation; (4) they provide a uniform force upon the capsular wall so as to reduce the chances of damaging the capsular wall; and (5) they reduce opacification by cell migration. From the above description, it can be understood that the implantation tool of this invention has several advantages, such as: (1) it improves the reliability of the implantation of lens in the posterior capsule; (2) it reduces the incidence of damage to flexible lens when implanted in the eye; and (3) it permits implantation through a very small opening within the capsular sac.

Although a preferred embodiment of the invention has been described with some particularity, many modifications and variations are possible in the preferred embodiment without deviating from the invention. Accordingly, within the scope of the appended claims, the invention may be practiced other than as specifically described.

What is claimed is:

1. A tool for implanting an intraocular lens comprising:

a uniform internal diameter injection tube having an injection opening on one end and a piston opening on the other end;

an entrance opening having a major axis in excess of ten millimeters and a minor axis smaller than eight millimeters whereby a lens implant may be positioned over the entrance with its diameter overlying only a portion of the major axis of the entrance opening but extending over the walls defining an elliptical opening;

said entrance section adjoining and having an aligned opening with the uniform injection tube opening; and

a piston means for moving the lens implant along the uniform internal diameter of the injection tube.

2. An implantation tool according to claim 1 further comprising a positioning tool having:

a thin depressing portion with a length slightly less than the major axis of said elliptical opening and a thickness less than the minor axis of the elliptical

opening wherein it may be utilized to push the lens into the entrance portion of the implantation tool; and

a long stem member for pushing the lens from the entrance portion into the uniform tubular injection portion.

3. The combination of an implantation tool and an intraocular lens implant comprising:

a tubular injection tube;

at least one lens body within the injection tube;

at least one position fixation member on the lens body;

the at least one lens body having a diameter less than said position fixation member and being positioned within said position fixation member;

the position fixation member and lens body being flexible wherein at least a portion of both the lens body and position fixation member may be folded;

said position fixation member being substantially ring-shaped;

a flexible connection means connecting said lens body with said position fixation member;

an elliptical entrance opening in the implantation tool; and

a plunger having a piston positioned to snugly move along the inside of the injection to inject a lens.

4. The combination of claim 3 in which:

said flexible connection means comprises a pair of elongated members extending oppositely from said lens body;

each of said elongated members having a substantial portion of its length which is substantially concentrically disposed with said position fixation member.

5. The combination of claim 3 in which said flexible connection means comprises a pair of closely spaced-apart posts extending from said lens body to said position fixation member and at least one elongated curved member extending from said lens body to said position fixation member.

6. The combination of claim 3 in which:

one loop member has one end secured to said lens body at approximately the three o'clock position and extending around the lens body in a spaced-apart relationship with respect thereto and has its other end

secured to said lens body at approximately the three o'clock position; and

the other of said loop members having one end secured to said lens body at approximately the nine o'clock position and extending around the lens body in a spaced-apart relationship with respect thereto and having its other end secured to said lens body at approximately the nine o'clock position.

7. A method of inserting a flexible, intraocular, lens implant into the capsular sac of the eye comprising the steps of:

making an incision of less than 7 millimeters in the capsular sac of the eye;

inserting a lens implant into a uniform tube;

inserting the uniform tube into the capsular sac through the incision;

injecting the lens implant into the capsular sac; and

contacting the capsular wall during normal use at locations entirely circumferentially to said at least one fixation member and lens body.

8. A method according to claim 7 further including the step of bending the lens implant before it is inserted through the incision.

9. A method of inserting a one-piece, flexible, intraocular, lens implant into the capsular bag of the eye comprising the steps of:

making an incision of less than 7 millimeters in the capsular bag of the eye;

removing a damaged lens;

compressing in a plane with the lens body said one-piece, flexible, intraocular, lens implant small enough for insertion into said incision into a uniform internal diameter tube;

inserting said tube into the capsular sac and injecting the one-piece, flexible, intraocular lens implant through the incision within said tube;

permitting said one-piece, flexible, intraocular, lens implant to expand in one plane within the capsular bag without causing damage to cells within the capsular bag wherein said one-piece, flexible, intraocular, lens implant maintains a substantially 360 degree contact within the capsular bag in a plane substantially perpendicular to the optical axis to provide a uniform force upon the capsular wall thereby reducing damage to

the capsular wall and reducing opacification by cell migration.

10. A method of inserting a composite, flexible, intraocular, lens implant into the capsular bag of the eye comprising the steps of:

making an incision of less than 7 millimeters in the capsular bag of the eye;

removing a damaged lens;

bending a first component lens implant and inserting through the incision with the aid of an implantation tool;

bending a second component lens implant and inserting it through the incision through the same tool;

mounting said first and second lens implants in the capsular sac one on the other wherein said first and second component lens implants has a different lens body with a diameter of between 4.0 millimeters and 8.0 millimeters, at least one corresponding fixation member and at least one corresponding connection member;

contacting the capsular wall during normal use at locations entirely circumferentially to said at least one fixation member and lens body of each component lens implant with the lens body being held flexibly at a central location within said at least one fixation

member wherein normal movement of the eye does not move said lens implant out of the optic axis of the capsular bag.

11. A method according to claim 10 in which the step of bending includes the step of rolling and the first component lens implant is unrolled before the record component lens implant is inserted through the incision.

12. A tool in accordance with claim 1 in which said piston means includes an end portion with a compartment wherein the end portion is movable with the piston means from a position under said entrance opening to a position just outside of said injection opening, whereby said piston means may receive a portion of said lens implant and move said lens implant outside of said injection opening for implanting.

13. A tool in accordance with claim 12 in which said compartment has an open portion substantially the same width as the width of said entrance opening and a length of one-half the length; said compartment's distal end being opened and there being a slot extending along the length of the compartment in a bottom wall of the

compartment opposite an upper opening of the compartment, wherein when the compartment extends outside of the uniform internal diameter injection tube, the compartment becomes larger;

said piston means being rotatable whereby it may be rotated 180 degrees after said lens implant has been inserted in the compartment.

14. A tool in accordance with claim 3 in which said piston includes an end portion with a compartment wherein the end portion is movable with the piston from a position under said entrance opening to a position just outside of an injection opening, whereby said piston may receive a portion of a lens implant and move said lens implant outside of said injection opening for implanting.

15. A tool in accordance with claim 14 in which said compartment has an open portion substantially the same width as the width of said entrance opening and a length of one-half the length; said compartment's distal end being opened and there being a slot extending along the length of the compartment in a bottom wall of the compartment opposite an upper opening of the compartment, wherein when the compartment extends

outside of the tubular injection tube, the compartment becomes larger;

said piston being rotatable whereby it may be rotated 180 degrees after said lens implant has been inserted.

16. A method in accordance with claim 9 in which the step of compressing in a plane with a lens body comprises the steps of:

forcing the lens implant through an opening of an implantation tool that includes said tube so that the compressed lens fits partly into the end of a piston and partly forward of the end of the piston;

pushing the piston forwardly into the tube with a portion of the lens ahead of the piston and a portion within the piston;

rotating the piston through 180 degrees;

inserting the piston into the capsular sac, wherein the lens unfolds into the capsular sac; and

withdrawing the piston.

FIG. 1

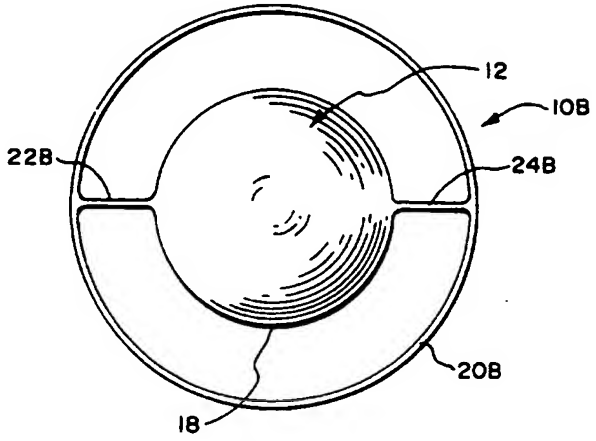
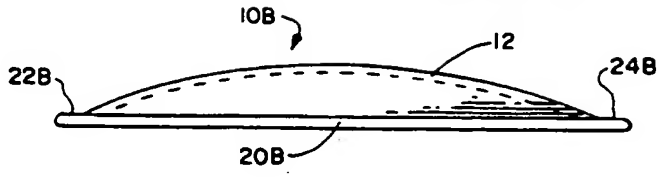


FIG. 2



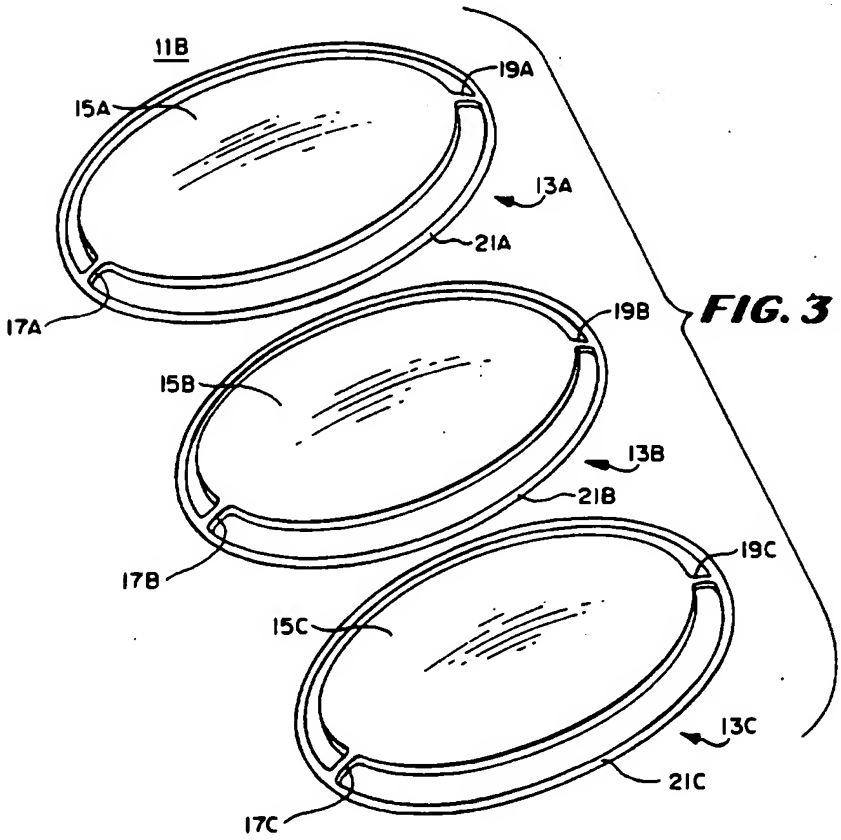


FIG. 3

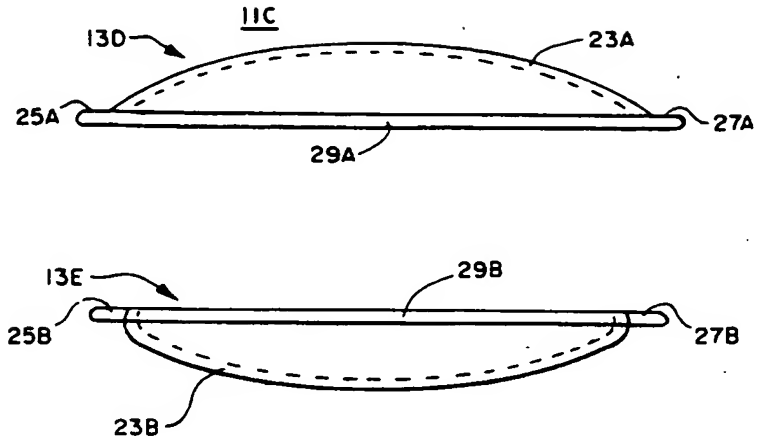


FIG. 4

FIG. 5

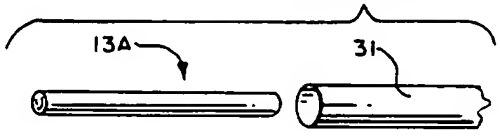


FIG. 6

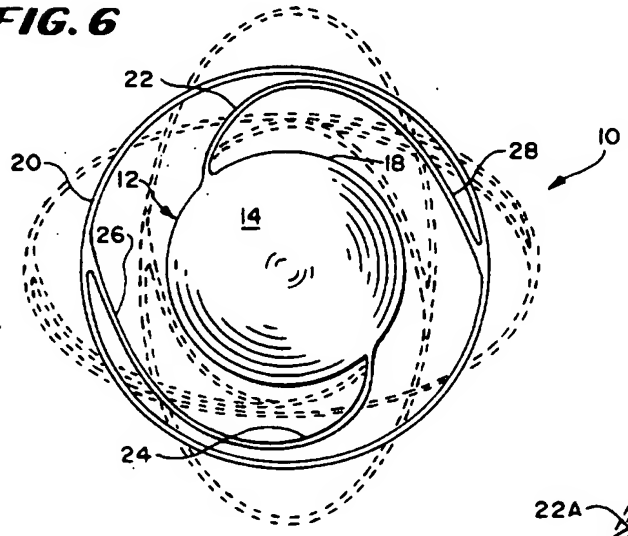


FIG. 7

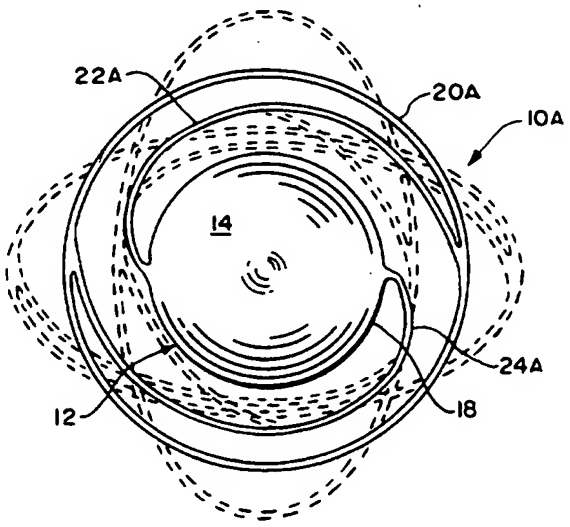


FIG. 8

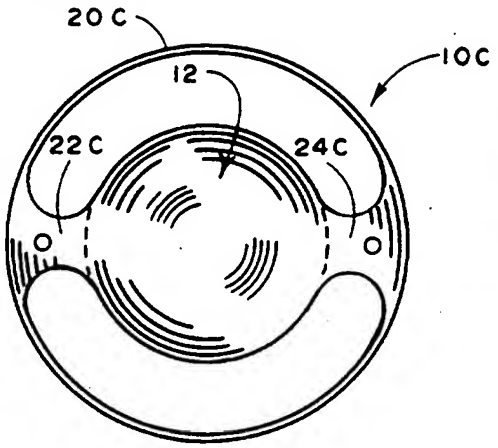


FIG. 9

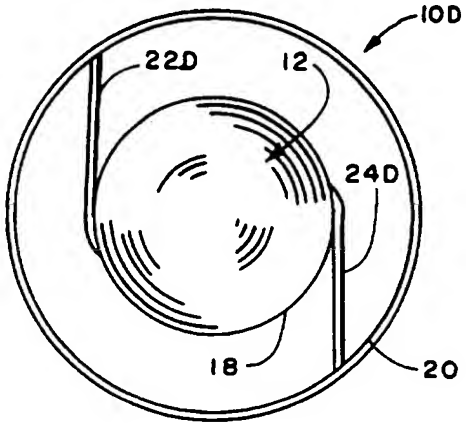


FIG. 10

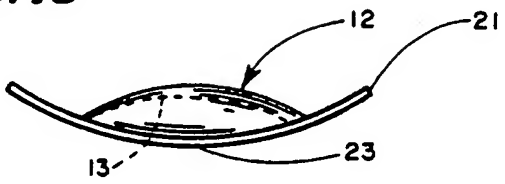


FIG. 11

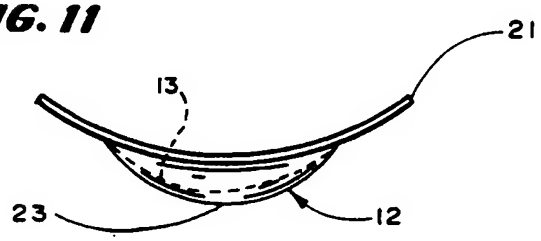


FIG. 12

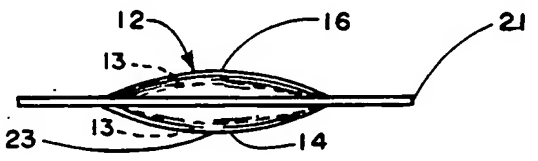


FIG. 13

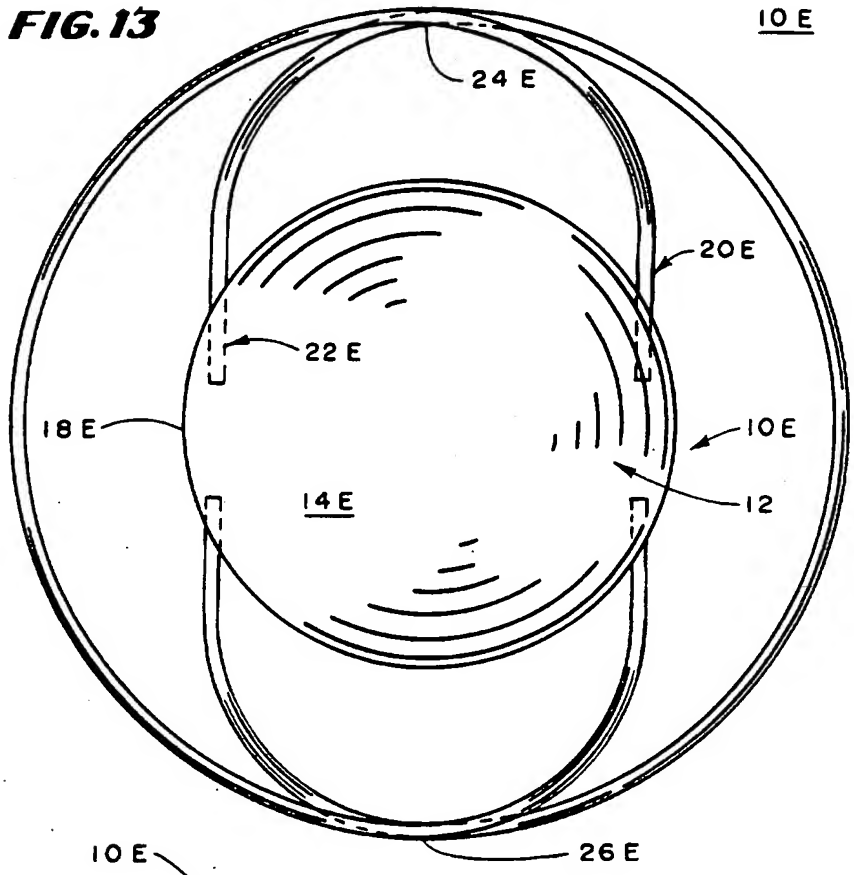


FIG. 14

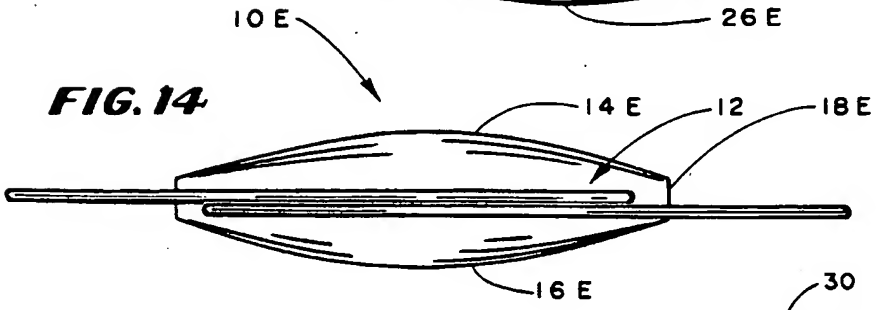


FIG. 15

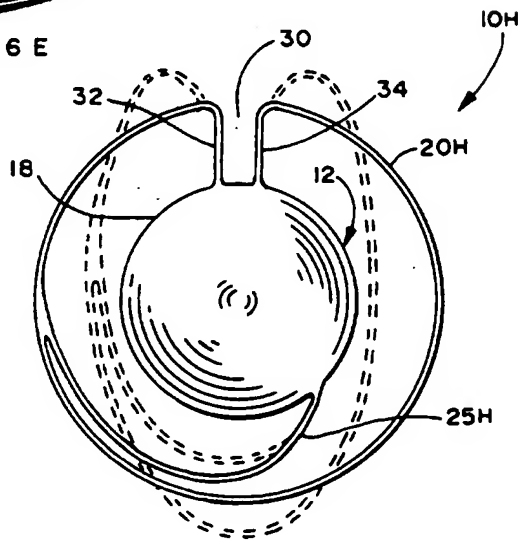


FIG. 16

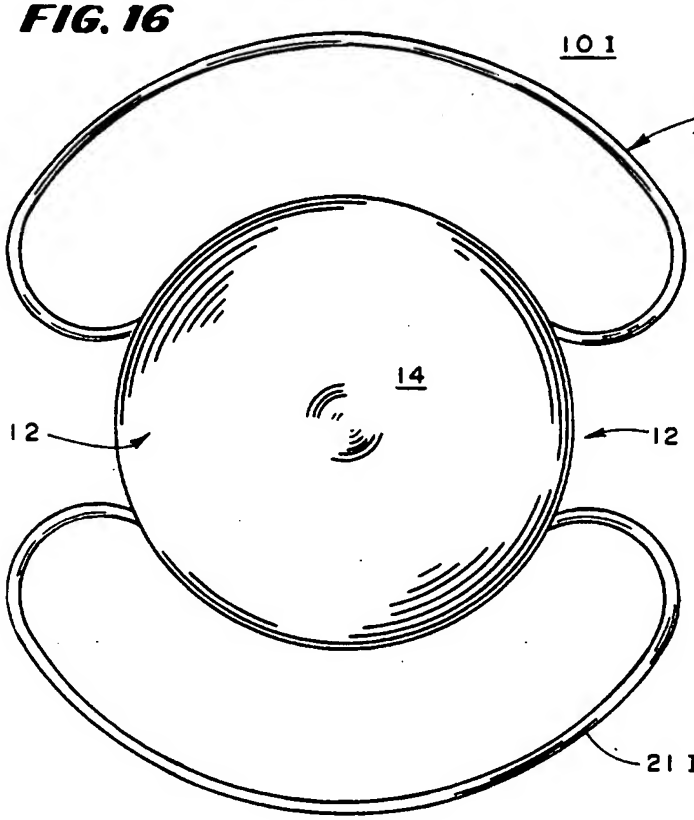


FIG. 17

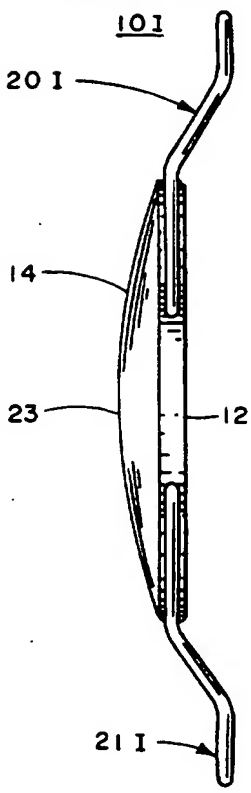


FIG 18

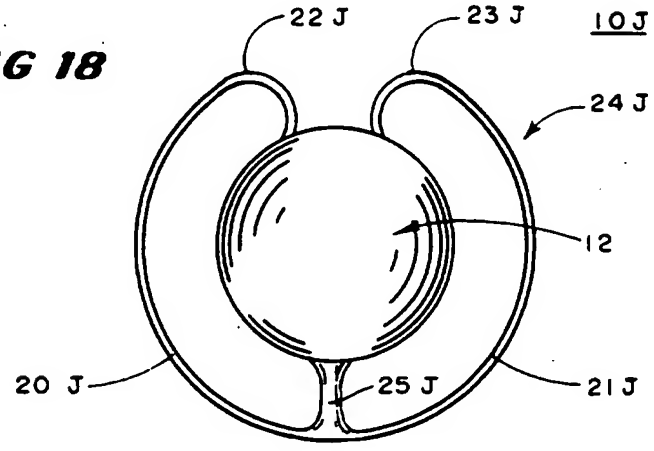


FIG. 19

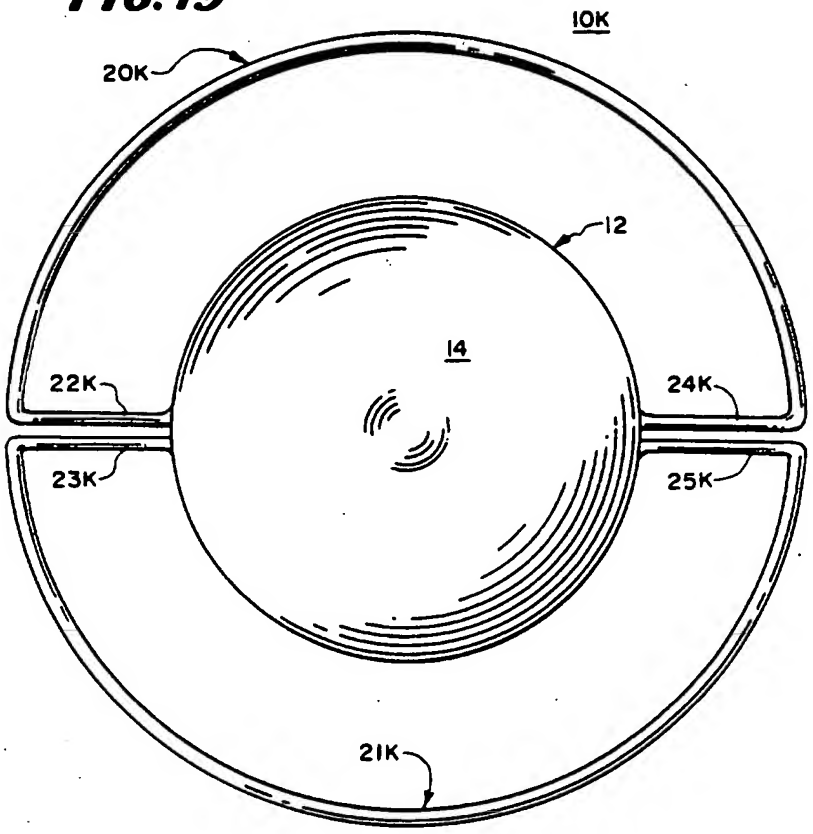


FIG. 20

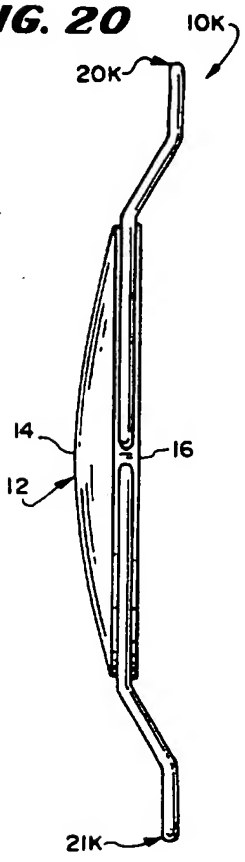


FIG. 21

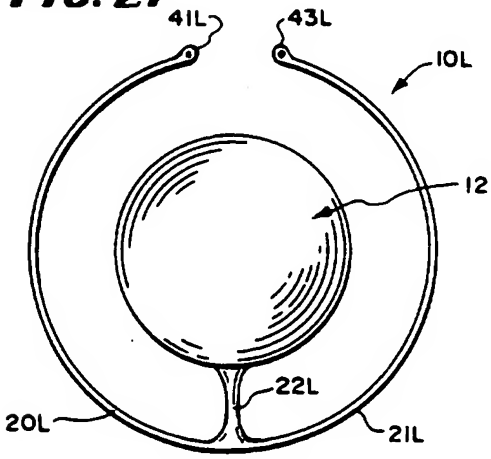


FIG. 22

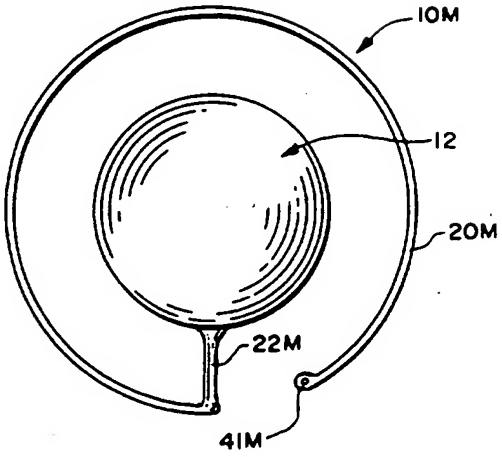


FIG. 23

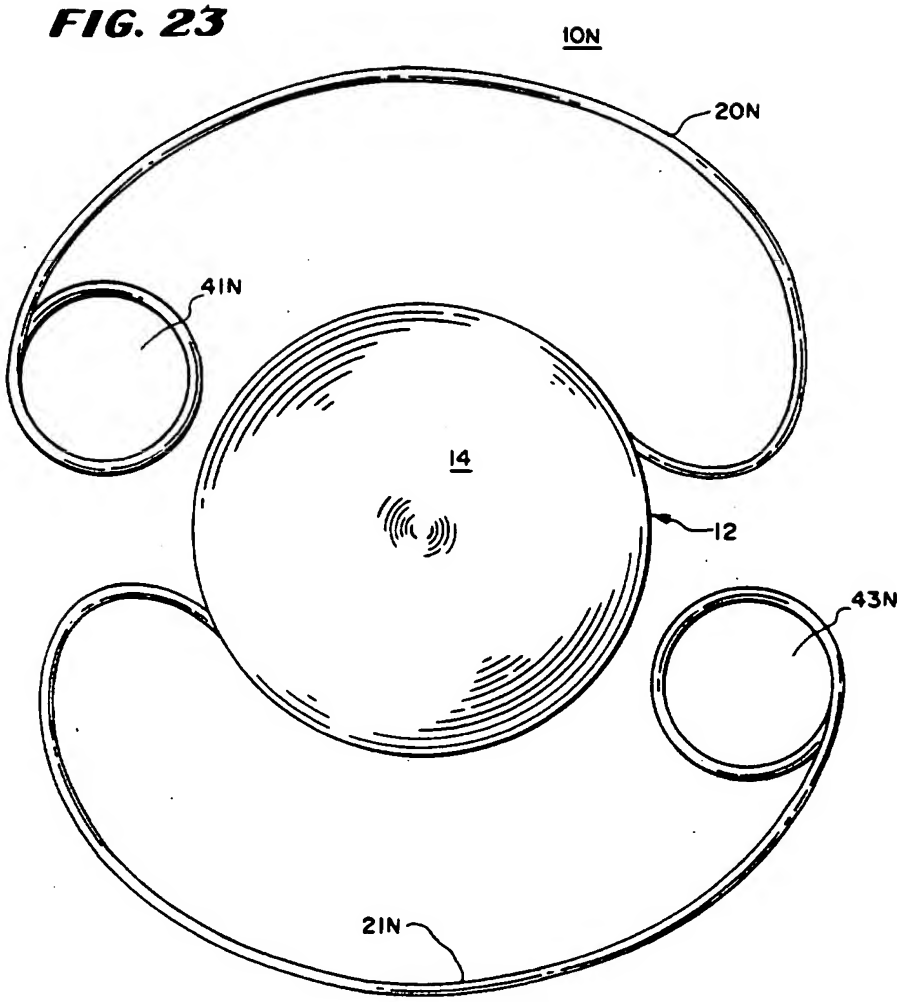


FIG. 24

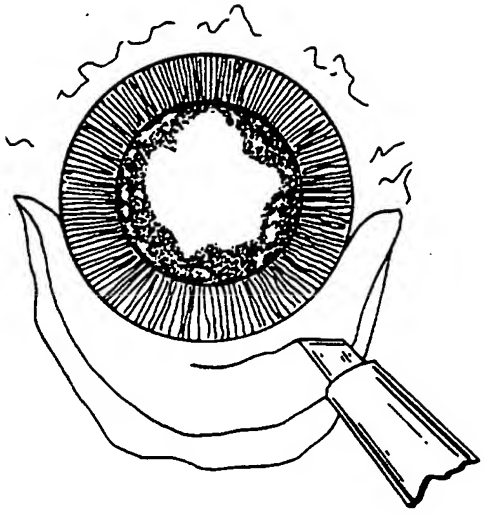


FIG. 25

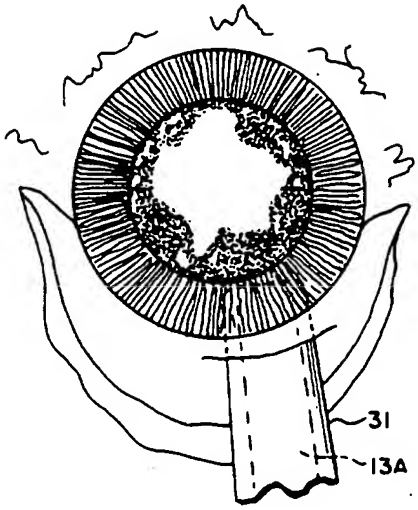


FIG. 26

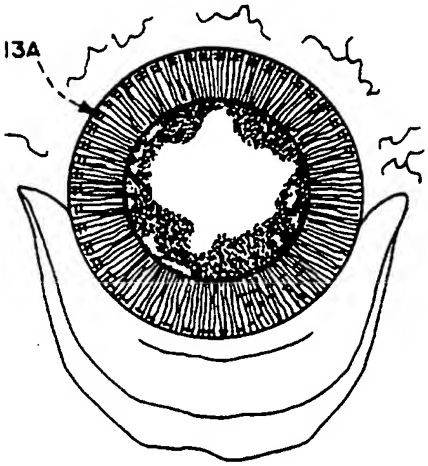
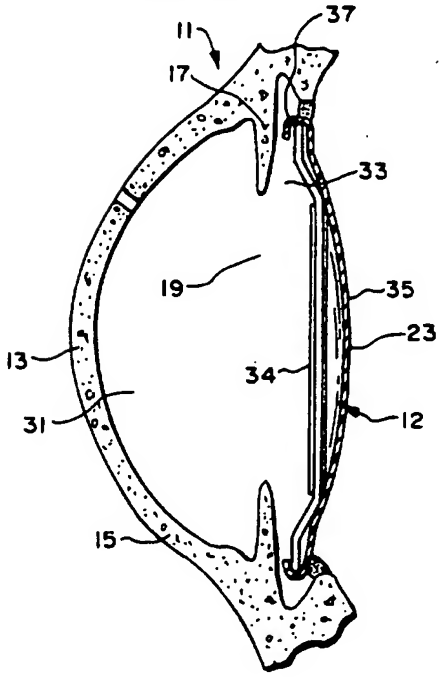


FIG. 27



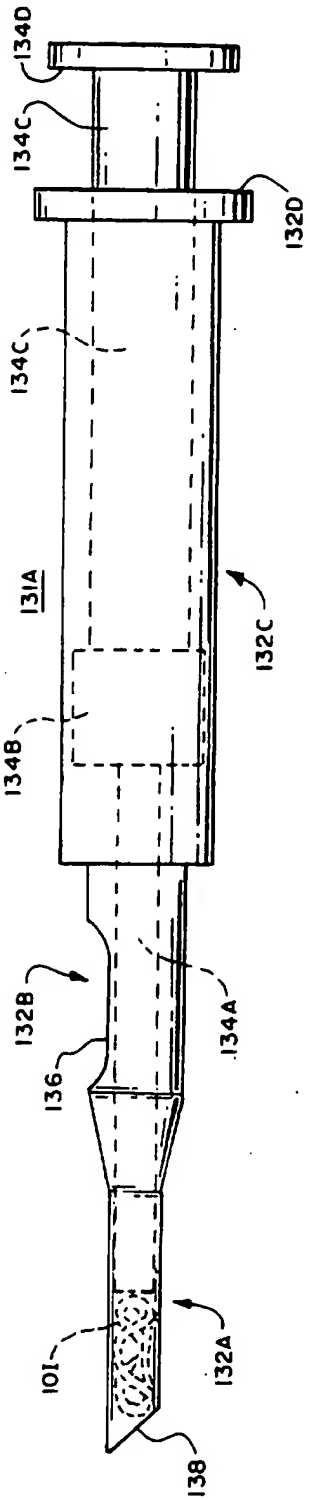

134D
134C
132D
134C
131A
132C
134B
132B
136
134A
101
132A
138

FIG. 28

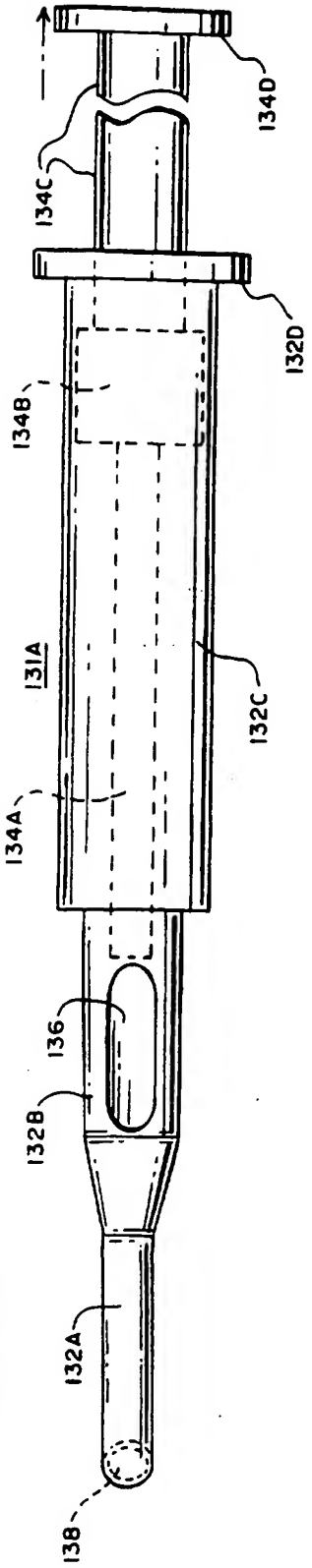

134D
134C
132D
134B
131A
132C
134A
136
132B
132A
138

FIG. 29

FIG. 30

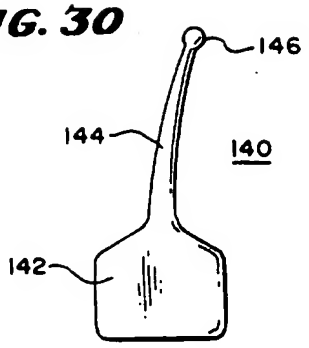


FIG. 31

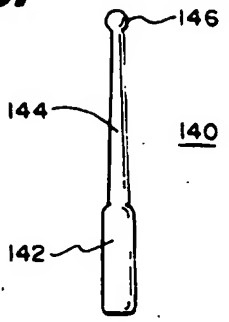


FIG. 32

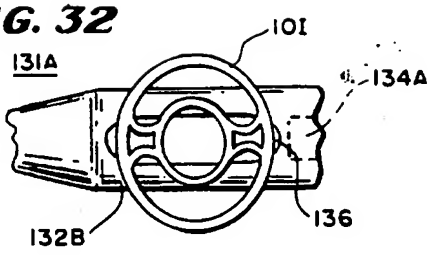


FIG. 33

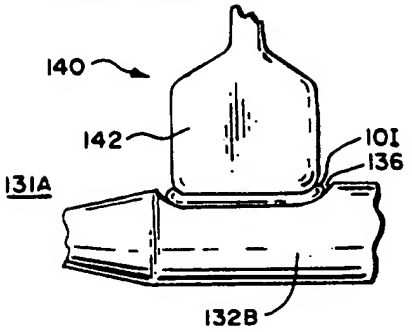


FIG. 34

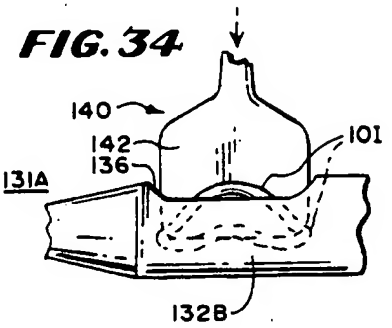
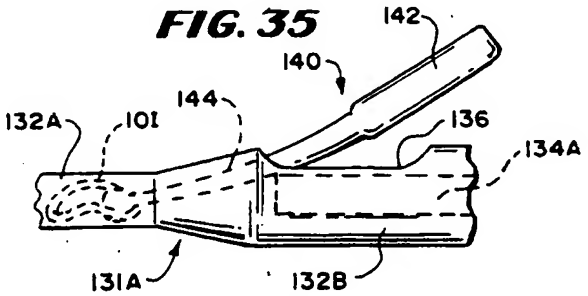


FIG. 35



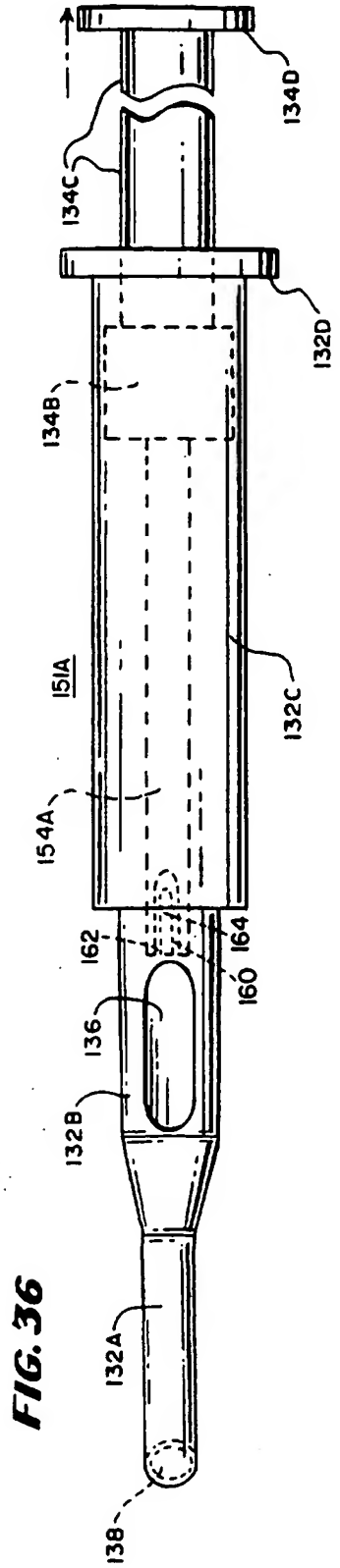


FIG. 36

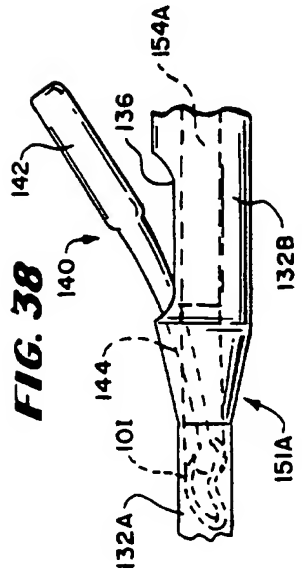


FIG. 38

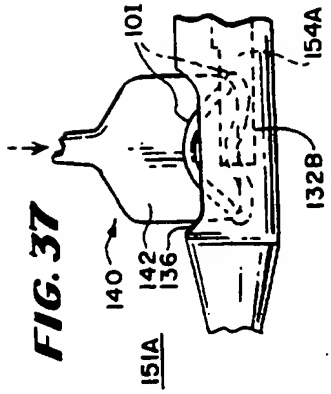


FIG. 37

INTERNATIONAL SEARCH REPORT

Interna al application No.
PCT/US96/04279

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61F 2/16
US CL :623/6

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 623/6; 606/107

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US, A, 4,573,998 (MAZZOCCO) 04 MARCH 1986, see Figure 38.	7-9 ----- 3-6, 16
Y	US, A, 4,681,102 (BARTELL) 21 JULY 1987, see entire document.	3-6
Y	US, A, 5,123,905 (KELMAN) 23 JUNE 1992, see Figures 1 and 3.	1
Y	US, A, 5,304,182 (RHEINISH ET AL.) 19 APRIL 1994, see Figure 2.	12, 16
Y	US, A, 4,863,463 (TJAN) 05 SEPTEMBER 1989, see entire document.	4
Y	US, A, 4,795,460 (ANIS) 03 JANUARY 1989, see entire	6

[X] Further documents are listed in the continuation of Box C. [ ] See patent family annex.

* Special categories of cited documents

"A" document defining the general state of the art which is not considered to be part of particular relevance

"E" earlier document published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
06 AUGUST 1996	23 AUG 1996

Name and mailing address of the ISA/US	Authorized officer
Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231	FOR MARY BETH JONES
Facsimile No. (703) 305-3230	Telephone No. (703) 308-0858

Form PCT/ISA/210 (second sheet)(July 1992)*

INTERNATIONAL SEARCH REPORT

Intern. ..al application No.
PCT/US96/04279

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US, A, 4,804,361 (ANIS) 14 FEBRUARY 1989, see entire document.	5
A	US, A, 4,765,329 (CUMMING ET AL.) 23 AUGUST 1988, see Figure 3.	1-16
A	US, A, 5,468,246 (BLAKE) 21 NOVEMBER 1995, see entire document.	1-16